United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Proposed Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products from Canada into the United States

Environmental Assessment, October 2003

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I. What is this document and why is it being prepared?

Consistent with the National Environmental Policy Act of 1969 (NEPA) (42 United States Code 4321 *et seq*.) and its implementing regulations (40 Code of Federal Regulations (CFR) Parts 1500–1508), as well as the implementing procedures of the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) (7 CFR Part 372), this environmental assessment (EA) explores potential environmental effects associated with a rulemaking proposal to allow some currently prohibited ruminants[1], ruminant products, and ruminant by-products to be imported from other countries where there is a minimal risk that bovine spongiform encephalopathy (BSE, also known as "mad cow disease") will thereby be introduced into the United States. Available evidence developed in risk analyses indicates that BSE is unlikely to become established in the United States. However, this EA considers, from an environmental quality perspective, the unlikely scenario that BSE could be introduced into this country.

II. What is the purpose of and need for the proposed action?

The purpose of the proposed action is to modify import regulations in order for the United States to allow the importation of ruminants, ruminant products, and ruminant by-products that do not substantially increase the risk of BSE entering the country. The need for the proposed action is to allow trade of certain live ruminants and ruminant products and by-products when there is no scientific basis for trade restrictions.

On May 20, 2003, the Canadian Food Inspection Agency (CFIA) reported a case of BSE in a beef cow in northern Alberta. The United States immediately added Canada to the list of regions where BSE is known to exist (9 CFR § 94.18(a)(1))**.** This action prohibited the importation of ruminants, ruminant products, and ruminant by-products that have been in Canada. After the U.S. import prohibition, Canada conducted an epidemiological investigation and implemented

[1] Any of various hoofed, even-toed, usually horned mammals such as cows, sheep, goats, deer, giraffes, and camels. They characteristically have a stomach divided into four compartments and chew cud.

additional risk mitigation measures. Thereafter, Canada requested that the United States allow the importation of certain low-risk live ruminants and ruminant products and by-products.

III. What alternatives are considered?

A. No action

The no action alternative would maintain the continued regulatory prohibition of the importation of animals, animal products, and animal by-products from Canada. The current regulations in 9 CFR Parts 93, 94, 95, and 96 prohibit the importation of live ruminants and most ruminant products and by-products from (1) regions where BSE exists (9 CFR § 94.18(a)(1)) and (2) regions that present an undue risk of introducing BSE into the United States via live ruminant or ruminant products or by-products because of inadequate surveillance or import requirements that are less restrictive than would be allowed for importation into the United States (9 CFR § 94.18(a)(2)).

B. Proposed action

The proposed rulemaking would allow for the importation of certain live ruminants and ruminant products and by-products, provided the requesting country seeking recognition as a minimal risk region demonstrates that it meets certain factors similar to the criteria recommended by the Office International des Epizooties (OIE)[2]. This action would continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on certain low-risk commodities from these regions. The factors that would have to be addressed, as determined by an evaluation, include evaluation of whether the region has complied with the following:

(1) Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

(a) Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and

[2] An organization that establishes international standards that facilitate trade for countries that are signatories to international trade agreements, while minimizing the risk of introducing diseases.

animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;
(b) Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE; and
(c) A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

(2) In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures; and
(3) In regions where BSE was detected, took additional risk mitigation measures, as necessary, following the BSE outbreak, and continues to take such measures.

CFIA has requested the United States to recognize Canada as a minimal risk BSE region, thus allowing imports of certain live ruminants and ruminant products and by-products into the United States. For the list of low-risk products and specific risk-reduction strategies associated with CFIA's request, refer to the risk assessment conducted by APHIS.

IV. What is BSE?

BSE, commonly referred to as "mad cow disease" is a slowly progressive, degenerative disease that affects the central nervous system (CNS) of adult cattle. BSE belongs to a family of diseases known as transmissible spongiform encephalopathies (TSEs). TSEs share some common characteristics, including a prolonged incubation period ranging from a few months to years and progressively debilitating neurological illnesses, which are always fatal. The typical incubation period for BSE is 2 to 8 years. Following the onset of clinical signs, the animal's condition deteriorates until it either dies or is destroyed. This process usually takes from 2 weeks to 6 months.

The causative agent of BSE has not been fully characterized, but three possibilities have been proposed: an unconventional virus, a prion (a self-replicating protein), or a virino (an incomplete virus). Currently, the most accepted theory is that the agent is a prion protein. The BSE agent is extremely resistant to heat, ultraviolet light, ionizing radiation, and common disinfectant processes, and it also does not evoke any detectable immune response or inflammatory reaction in host animals. Transmission of BSE is believed to be spread to cattle through

consumption of contaminated meat and bone meal from cattle with previously unidentified BSE. Tissues of particular risk include, but are not limited to, the brain, spinal cord, and eyes. BSE does not appear to be transmitted via contact between cattle or between cattle and other TSE-affected species. Some evidence suggests that maternal transmission may occur at an extremely low level (Wilesmith *et al.*, 1997).

V. What are the risks that BSE could be introduced into this country?

A. Under the current regulatory system

No cases of BSE have been detected in the United States under the current regulatory system. Because the primary source of transmission of BSE has been shown to be proteins derived from BSE-infected cattle in feed, the Food and Drug Administration (FDA), in 1997, established regulations that prohibit the feeding of most mammalian proteins to ruminants in the United States. To prevent BSE from entering the United States, since 1989, APHIS has restricted importation of live ruminants and ruminant products and by-products (e.g., fetal bovine serum, meat-and-bone meal, bonemeal, bloodmeal, offal, fats, and glands) from countries where BSE has been diagnosed. Because of concerns about cross-contamination of rendered products of nonruminant origin with the BSE agent, APHIS, since 2000, also has prohibited all imports of rendered animal protein products, regardless of species, from BSE-infected countries.

A risk assessment (Cohen *et al.*, 2001), "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," by the Harvard Center for Risk Analysis and Tuskegee University (hereafter referred to as the Harvard risk assessment), found that, owing to the already ongoing Federal programs, the United States is highly resistant to the spread of BSE in cattle herds and humans. The Harvard risk assessment regarded the feed ban as the United States' most effective means of BSE prevention.

B. Under the proposed action

The proposed rulemaking includes factors that address the same issues addressed by the criteria of the Office International des Epizooties (OIE) for minimal risk classification.

Canada maintains it generally meets the OIE criteria for a minimal risk country. Specifically, the OIE code (OIE 2002) provides for countries with indigenous cases of BSE to be categorized as minimal, moderate, or high risk based on established criteria. The primary differentiating standard for these designations is the incidence rate of indigenous cases. For a minimal risk country, the incidence rate must have been less than one case per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age. The incidence rate for Canada has been 0 for 3 years and one animal in 5.5 million over the last 12-month period. This is within the parameters for a minimal risk country, and well below the parameters for a moderate risk country.

OIE criteria currently require that a country has had an effective feed ban in place for 8 years. The feed ban in Canada has been in place for 6 years. However, Canada has submitted evidence to show a history of stringent import control measures since 1990, a strong surveillance system since 1992, and appropriate additional mitigation actions taken as necessary. Canada recently added an additional measure, in response to the BSE find, to enhance food safety controls regarding BSE. The new measure requires that specified risk materials (SRM) be removed from cattle at time of slaughter. SRM are tissues that, in BSE-infected cattle, contain the agent that may transmit the disease. In addition, Canada has had a regulatory system for beef slaughter and processing that has been deemed equivalent to the U.S. system.

The APHIS risk assessment describes the risk-reduction strategies, that would provide multiple firewalls against BSE. The risk assessment conducted by APHIS concluded that with the surveillance, prevention, and control measures implemented by Canada, and the additional mitigations for specific animals and animal products intended for import, the risk of BSE being imported into the United States from Canada would be low.

VI. What are the nature and extent of environmental effects that may be expected if BSE were introduced into this country?

According to the NEPA implementing regulations, criteria set forth in 40 CFR § 1508.27(b) should be considered in this environmental assessment. Not all criteria are applicable; those that are applicable will be considered below, principally for the proposed action. The

degree to which the no action alternative potentially could adversely affect all aspects of environmental quality being considered, while not zero, is less than that associated with the proposed action. Further discussion will focus only on potential environmental effects associated with the rulemaking proposal.

A. The degree to which the proposed action affects public health or safety (40 CFR § 1508.27(b)(2)).

There appears to be a causal link between variant Creutzfeldt-Jakob (vCJD), a TSE that affects humans, and the consumption of beef products contaminated with the BSE agent. A small number of vCJD cases has been reported, primarily in the United Kingdom, occurring in people who consumed beef that may have been contaminated. As of May 2003, a total of approximately 139 cases of vCJD have been reported worldwide. The one reported case of vCJD in the United States was of a woman who contracted the disease while residing in the United Kingdom. The symptoms appeared years later after the woman moved to the United States.

1. Actions to protect public health and safety if BSE is found in the United States

APHIS and FSIS developed a step-by-step action plan in the event a case of BSE were to be detected in the United States. The plan outlines those events that should take place, including identification of a suspect animal, confirmation, the epidemiologic investigation, animal and herd disposition activities, and communication of information. The plan has been shared with other government agencies that have developed their own plans to coordinate with those of APHIS. A summary of the BSE response plan is available on the Internet at the following web site: http://www.aphis.usda.gov/lpa/issues/bse/bsesum.pdf.

The BSE Emergency Disease Guidelines detail acceptable disposal methods that should be used to dispose of BSE-suspect carcasses. The methods are incineration and burial. BSE-suspect carcasses and confirmed carcasses are not allowed to be rendered due to the possible spread of the disease to animals and the public.

Incineration of carcasses and other infected materials is expected to destroy most of the BSE-agent. The incinerators are designed to attain operating temperatures of 1800 °C to 2800 °C. These high temperatures at the stack flue eliminate nearly all smoke and

particulates. Emissions pose little if any air contamination concerns. The remaining ash is expected to be generally free of toxic substances, but there may be some viable BSE agents in the ash due to variability of incineration temperature within the unit and incomplete combustion of all materials burned. Proper collection and disposal of ash in a sanitary landfill should eliminate any residual BSE agents.
Burial is allowed only if no other avenues for carcass disposal are available. The burial site may be on the affected farm, at the diagnostic laboratory where the carcass is examined, or in a sanitary landfill. Burial trenches are at least 9 feet deep with floor dimensions of 7×2 feet per adult bovine carcass. The carcasses should be covered with at least 6 feet of soil to avoid attracting wildlife that could possibly spread the disease. The soil should not be too tightly packed to avoid leakage of gas formations from the cracked soil. Burial sites are required to be a sufficient distance away from utility lines and water sources; they must not be used for agricultural purposes and must be properly protected to keep out humans and animals.

The primary concerns relate to the ability of sanitary landfills to contain any remaining infective BSE agent or other potentially hazardous substances associated with dead stock and to prevent any runoff to surface water or any leaching to groundwater. The linings of sanitary landfills are such that movement of the BSE agent or other substances is largely precluded. These facilities are required to adhere to water quality standards set by the U.S. Environmental Protection Agency and State agencies. Contamination of soil or water outside the landfill line is not anticipated. The landfill sites are located at undisturbed locations where access is restricted to landfill managers. The enclosures surrounding the landfill should keep out most people and wildlife.

2. Preventive actions to protect public health and safety

The Harvard risk assessment identified three pathways or practices that could contribute most either to increased human exposure to the BSE agent or to the spread of BSE if it should be introduced into the United States. The pathways or practices are (1) noncompliance with the feed ban, (2) rendering of downer cattle (cattle that cannot rise from a recumbent position) including cattle that die on the farm, and (3) inclusion of high risk tissue, such as brain and spinal cord, in edible products.

Because the primary source of transmission of BSE has been shown to be proteins derived from BSE-infected cattle in feed, the Food and Drug Administration (FDA) has established regulations that prohibit

the feeding of most mammalian proteins to ruminants in the United States. To prevent BSE from entering the United States, since 1989, APHIS has restricted importation of live ruminants and ruminant products (e.g., fetal bovine serum, meat-and-bone meal, bonemeal, bloodmeal, offal, fats, glands) from countries where BSE has been diagnosed. Also, because of concerns about cross-contamination of rendered products of nonruminant origin with the BSE agent, since 2000, APHIS also has prohibited all imports of rendered animal protein products, regardless of species, from BSE-infected countries.

Cattle sent for slaughter in the United States are evaluated by the USDA's Food Safety and Inspection Service (FSIS) for signs of neurologic disease. Cattle exhibiting neurological signs on antemortem inspection are condemned and are not used for human food. Central nervous system tissue from these animals is forwarded to APHIS laboratories for pathologic examination.

In summary, given (1) the relatively low initial (pre-filing) risks, including the attenuated nature of the pathways through which the disease would be communicated, (2) the risk-reduction strategies developed in the APHIS risk assessment, (3) the APHIS action plan to deal with BSE were it to be discovered in the United States, and (4) the heightened vigilance on both sides of the border stemming from this proceeding, approval and implementation of the proposal, particularly as applied to Canada, could not be viewed as increasing significantly the risk of potentially adverse public health effects.

B. The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks (40 CFR § 1508.27(b)(5)).

The exact quantitative relationship between human exposure to BSE agents and the likelihood of human disease is unknown; the likelihood that humans will develop vCJD under various scenarios is entirely speculative and cannot be assessed. Similarly, potential human exposure to the BSE agent through products containing ingredients of bovine origin, such as some pharmaceuticals, gelatin, beef stocks, extracts, and flavorings are not addressed in the Harvard risk assessment. If BSE should enter the United States, the Harvard risk assessment indicates that, at most, probably only a small amount of potentially dangerous tissues would reach the human food supply.

The Harvard risk assessment reports some uncertainty with regard to the misfeeding rate on farms and estimating the spread of BSE among

cattle. Misfeeding prohibited feed (containing ruminant protein) to cattle on farms that raise both cattle and either pigs or chickens completely compromises the feed ban. A second source of uncertainty associated with the feed ban is the proportion of feed produced that is mislabeled. The study finds that even if BSE were to occur in the United States, because of FDA's feed ban, very little of the BSE agent that potentially could get into the U.S. cattle herds would enable an outbreak from sick animals to healthy ones.

C. The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration (40 CFR § 1508.27(b)(6)) and whether the action is related to other actions with individually insignificant but cumulatively significant impacts (40 CFR § 1508.27(b)(7)).

Implementation of the proposed rule, particularly as applied to Canada, will set a precedent for future actions by establishing criteria through which other BSE-infected countries may submit requests to import certain live ruminants and ruminant products and byproducts that meet the criteria for being unlikely to contain the BSE infectious agent. At this time, it is speculative as to which BSE-infected countries or how many countries would request recognition and meet the minimal-risk criteria. While the potential cumulative effects of this proposed action cannot be predicted, each petition that APHIS receives from a country would require an assessment of the environmental effects of the petitioned action in combination with the actions of all countries whose requests previously have been approved. Monitoring the potential environmental impacts in this manner is both practical and meaningful and would allow APHIS to revisit the issue of cumulative effects with each filing.

D. The degree to which the action may adversely affect an endangered or threatened species or its habitat (40 CFR §1508.27(b)(9)).

Endangered Species Act. Section 7 of the Endangered Species Act (ESA) and ESA's implementing regulations require Federal agencies to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat.

Transmissible spongiform encphalopathies have been reported in Europe in captive wild ruminants, cats, and monkeys and are believed to have resulted from BSE-contaminated feed. Six endangered ruminant species were considered as potentially affected by this proposed rule as a result of the possibility of contact by these wild species with BSE-infected cattle or ingestion of contaminated feed (see table 1).

Table 1. Endangered wild ruminant species in the United States at risk from transmissible spongiform encephalopathies.

Common Name	Scientific Name	Listing Status
Woodland caribou	*Rangifer tarandus caribou*	Endangered
Columbian white-tailed deer	*Odocoileus virginianus leuceurus*	
Key deer	*Odocoileus virginianus clavium*	
Sonoran pronghorn	*Antilocapra americana sonoriensis*	
Bighorn sheep	*Ovis canadensis*	
Sierra Nevada bighorn sheep	*Ovis canadensis californiana*	

No evidence is available to show that BSE is spread by contact between unrelated cattle or from cattle to other species. In addition, animal feed imported from Canada that might be fed to wild ruminants in the United States will not contain BSE-contaminated animal products. The Food and Drug Administration has established regulations that prohibit the feeding of most mammalian proteins to ruminants in the United States. Thus, no effect is anticipated on listed wild ruminant species potentially susceptible to transmissible spongiform encephalopathies.

One threatened and three endangered wild cats were considered for risk of infection from BSE because of the possibility that they could feed on BSE-infected cattle or carcasses of cattle (see table 2).

Table 2. Listed wild cats known to feed on domestic cattle or cattle carcasses.

Common Name	Scientific Name	Listing Status
Jaguar	*Panthera onca*	Endangered
Canada lynx	*Lynx canadensis*	Threatened
Florida panther	*Puma (=Felis) concolor coryi*	Endangered
Eastern puma (=cougar)	*Puma (=Felis) concolor couguar*	

Based upon the effectiveness of the criteria included in the proposed rule to reduce BSE risk as determined by the risk assessment and the ability of the BSE Emergency Disease Guidelines to isolate and eliminate BSE should it be discovered in cattle in the United States, implementation of the proposed rule is not expected to have any effect on federally listed wild cats or their habitats.

VII. What are the conclusions?

The risk of introducing BSE into the United States as a result of the proposed rulemaking is low. Therefore, allowing certain live ruminants and ruminant products and by-products to be imported from minimal risk BSE regions should not significantly affect the quality of the human environment.

VIII. What agencies and persons have been consulted?

Regionalization Evaluation Services
National Center for Import and Export
Veterinary Services, APHIS, USDA

Emergency Programs
Veterinary Services, APHIS, USDA

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